

REMARKS

Claims 1-18, 20-25, 27 and 29-46 are currently pending, claim 43 having been amended. New claims 44-46 have been added.

Interview Summary

The Examiner is thanked for the personal interview conducted with applicants' undersigned representative on 26 March 2008. While no agreement was reached regarding the art rejection, the interview was beneficial to advance prosecution. The Examiner and applicants' undersigned representative reached an understanding that the claim recitation "wherein the lipid phase is non-polar" does properly comply with the written description requirement. As stated in paragraph [0038] of the patent application publication:

By "lipid" is meant a water-insoluble organic molecule with a fatty character. Suitable lipids for the preferred embodiments of the present invention include petroleum-derived lipids, synthetic lipids, and animal- and plant-derived lipids.

As agreed upon in the Interview, it is an inherent quality of lipids that they are "non-polar." Accordingly, the asserted 35 U.S.C. § 112, first paragraph, rejection is respectfully requested to be withdrawn.

Claim Amendments

Claim 43 has been amended to recite that the hygiene tissue is adapted to transfer living one or more lactic acid producing bacterial strains to a user. Further, new claims 44-46 have been added, which depend from claims 1, 21, and 23, respectively, which recite that the hygiene tissue is adapted to transfer living one or more lactic acid producing bacterial strains to a user.

Support for this amendment and the new claims may be found throughout the specification. Entry and consideration of the amendment and new claims are respectfully requested.

§ 103(a) Rejection - Gordon in view of Farmer

Claims 1-18, 20-25, 27 and 29-42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gordon (USPN 5,763,332) in view of Farmer (WO 01/13956). Applicants respectfully traverse this rejection.

The Examiner has asserted a rejection based on Gordon in view of Farmer. Gordon allegedly teaches a cleansing wipe with a high internal phase inverse emulsion. Farmer allegedly teaches a towelette with Emu Oil and lactic-acid producing bacteria (LAB).

However, the Examiner has failed to allege a combination that will result in the presently claimed invention. For at least this reason the rejection is improper.

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As discussed in the interview, the Examiner is relying upon Gordon as shown in Figure 5:

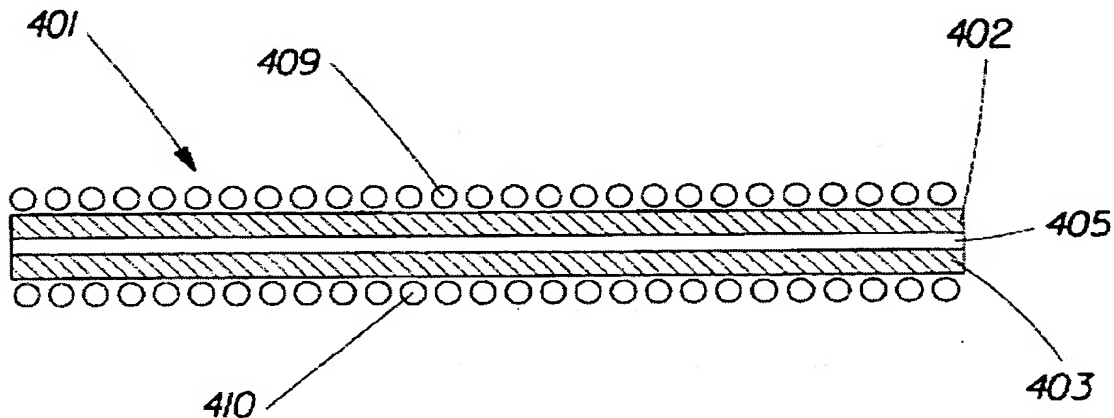


Fig. 5

According to Gordon, "FIG. 5 is a cross-sectional view of another article of the present invention where the internal phase comprises a significant level of water. Article 401 comprises a hydrophobic layer 405 which is a film formed from polyethylene or polypropylene. One surface of hydrophobic layer 405 is attached to a first hydrophilic paper substrate 402. An emulsion layer 409 is applied to hydrophilic substrate 402. The other surface of hydrophobic layer 405 is attached to a second hydrophilic substrate paper 403. Another emulsion layer 410 is applied to hydrophilic substrate 403." Column 5, lines 25-35.

In Figure 5, the Examiner has asserted that

- emulsion 409 corresponds to the claimed cleaning solution; and
- emulsion 410, modified with the LAB of Farmer, corresponds to the claimed lipid/LAB preparation.

Emulsion 410 (the alleged lipid/LAB preparation) is a high internal phase inversion emulsion. The high internal phase inverse emulsion of Gordon has three components (1) a continuous solidified external lipid; (2) an emulsifier that forms the emulsion when the external lipid phase is fluid; and (3) an internal polar phase dispersed in the external lipid phase. See column 11, lines 62-65. The internal polar phase is disclosed to be preferably water or, alternatively, an alcohol or glycol. See column 13, line 52 to column 14, line 59. **Water** - For the asserted combination to have the claimed water activity (see discussion below), the internal polar phase cannot be water. **Alcohol/Glycol** - One skilled in the art would understand that (non-water) embodiments disclosed in Gordon for the internal polar phase would be harmful to the lactic acid producing bacteria.

Water Activity - Water activity or a_w is a measurement of the energy status of the water in a system. It is defined as the vapor pressure of water divided by that of pure water at the same temperature; therefore, pure distilled water has a water activity of exactly one. See *Declaration of Dr. Håkansson*, paragraph 3. Water activity better predicts the growth of microorganisms because microorganisms can only use "available" water. See *Declaration of Dr. Håkansson*, paragraph 3. Thus, the water activity is not inherent to LAB, but is a feature of a preparation as a whole. See *Declaration of Dr. Håkansson*, paragraph 3.

The presently claimed invention recites that the lipid/LAB preparation has a water activity of 0.3 or less. As explained above, this a property of the preparation and not the LAB. Experiments have been conducted to show the effect of increased water activity on the survival rate of LAB. As shown in the *Declaration of Dr. Håkansson*, dry Lactobacillus in oil or petrolatum were stored in a dry atmosphere (sample 106-109) – the storage stability is very good. In the cases where the Lactobacillus in oil or petrolatum were stored in high humidity (sample 110-113) – the humidity has reached the Lactobacillus granules – increased water activity and hereby also dramatically decreased the storage stability. See *Declaration of Dr. Håkansson*, paragraphs 4-6.

Alcohol/Glycol - Alcohols, ethanol for example, are known to be effective antimicrobials. See *Declaration of Dr. Håkansson*, paragraph 7. Alcohols exhibit

rapid broad spectrum antimicrobial activity. See *Declaration of Dr. Håkansson*, paragraph 7. Glycols, such as propylene glycol, hexylene glycol and 1,3-butylene glycol, are known to have antimicrobial properties. See *Declaration of Dr. Håkansson*, paragraph 7. Additionally, polyethylene glycol has been shown to have significant antibacterial activity. See *Declaration of Dr. Håkansson*, paragraph 7.

With the above background in consideration, applicants respectfully assert that one skilled in the art would not have added the LAB of Farmer to the high internal phase inverse emulsion (emulsion 410, for example) in order to arrive at the presently claimed invention. As discussed above, the emulsion of Gordon has an internal polar phase which is water and/or alcohol/glycol.

The water option of the internal polar phase of Gordon would result in an LAB preparation that has a water activity much greater than 0.3 a_w and would cause a very short life expectancy for the LAB.

Using an alcohol or glycol as the internal polar phase of Gordon would result in an LAB preparation that is harmful to the LAB.

Dr. Håkansson has reviewed Gordon, and provides the following comments regarding Example VI of Gordon (Example VI was selected because it has the lowest percentage water):

I have reviewed Example VI of Gordon. Considering Example VI of Gordon, please note that, generally, Lactobacillus (LB) that is freeze-dried has a long shelf life if it is kept at room temperature and away from humidity, oxygen and heat.

Example VI of Gordon presents an absorbent article with a high internal phase emulsion. Of the high internal phase emulsion, 88.5% of the emulsion is an internal polar phase. The polar phase has (percentage given as percentage of the emulsion):

Sodium Carbonate - 0.5%
Preservative - 0.5%
Denatured Ethanol - 40%
Distilled Water - 47.5%

With the water content of 47.5%, the lactobacillus will absolutely have a very short survival (just some days) in room temperature as the water activity will be far above 0.3 a_w . There is also 40% ethanol that is, as anyone skilled in the art of working with microorganisms would know, very harmful for the survival of lactobacillus or any other bacteria. Ethanol is often used to kill bacteria.

Lactobacilli in a freeze-dried powder can survive (in room temperature) if the formulation has a very low water-activity i.e., below 0.3. In example VI in Gordon, there is a very high amount of both water and ethanol and there is nothing in the formulation that is able to bind the water and/or ethanol to reduce the water activity to a low level. Compared to freeze-dried lactobacilli in a lipid phase with a water activity of 0.3 a_w or less, the survival of lactobacilli in example VI is much worse.

It is not necessary to do any experiments replicating Example VI of Gordon, since the above remarks are common knowledge to anyone skilled in the art of working with microorganisms.

See *Declaration of Dr. Håkansson*, paragraphs 8 -12.

Thus, it is quite clear that one skilled in the art reading Gordon would not be motivated to incorporate a lactic acid producing bacteria in the high internal phase inverse emulsion of Gordon. Accordingly, one skilled in the art would not combine Gordon and Farmer in the manner asserted by the Examiner.

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Claim 21 recites, *inter alia*, that the first part and the second part are separate sheets joined together along two opposite side edges. And, claim 23 recites, *inter alia*, that the second part comprises a first sheet and a second sheet joined together along two opposite side edges and the first part comprises a sheet joined to one of said opposite side edges of the second part and extending along said side edge with one of a side edge of the sheet of the first part

A combination that includes each feature of claim 21 or claim 23 has not been disclosed or suggested. Further, the Examiner has failed to allege these combinations. The Examiner is respectfully requested to specifically identify where in Gordon (or other cited art) disclosure of the above-identified claim recitations may be found. Applicants respectfully assert that a proper *prima facie* case of obvious has not been presented.

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Claims 1, 21, 23 and 43 recite, *inter alia*, that the lipid phase is non-polar.

Gordon relates to a high internal phase inverse emulsion. The high internal phase inverse emulsion of Gordon has three components (1) a continuous solidified external lipid; (2) an emulsifier that forms the emulsion when the external lipid phase

is fluid; and (3) an ***internal polar phase*** dispersed in the external lipid phase. See column 11, lines 62-65.

Accordingly, the proposed combination relies upon an emulsion with an internal polar phase. However, the presently claimed invention is directed to a ***non-***polar lipid phase. Accordingly, the combination of Gordon and Farmer does not teach or suggest the presently claimed invention.

--Summary--

The Examiner has failed to allege a combination that will result in the presently claimed invention.

The internal polar phase (of the high internal phase inverse emulsion) of Gordon would be harmful to the lactic acid producing bacteria. Accordingly, one skilled in the art would not combine Gordon and Farmer in the manner asserted by the Examiner. The asserted art does not teach or suggest a preparation of lactic acid producing bacteria having a water activity of 0.30 or less.

A combination that includes the claimed structural features has not been disclosed or suggested.

The proposed combination relies upon an emulsion with an internal polar phase. However, the presently claimed invention is directed to a non-polar lipid phase.

Accordingly, the rejection of claims 1-18, 20-25, 27 and 29-42 as being unpatentable over Gordon (USPN 5,763,332) in view of Farmer (WO 01/13956) is respectfully requested to be withdrawn.

Conclusion

For the reasons stated above, it is requested that all the rejections be withdrawn and that this application be allowed in a timely manner.

Should any questions arise in connection with this application or should the Examiner feel that a teleconference with the undersigned would be helpful in resolving any issues pertaining to this application, it is requested that the undersigned be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By:

T.D. Boone

Travis D. Boone

Registration No. 52635

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620